This document is scheduled to be published in the Federal Register on 10/20/2015 and available online at http://federalregister.gov/a/2015-26392, and on FDsys.gov

[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Announcement of Requirements and Registration for The Open Science Prize

Authority: 15 U.S.C. 3719

AWARD APPROVING OFFICIAL: Philip E. Bourne, Associate Director, NIH OD

SUMMARY: The National Institutes of Health (NIH) Office of the Associate Director for Data Science (ADDS) announces a collaboration with the Wellcome Trust (WT) and the Howard Hughes Medical Institute (HHMI) to launch the "Open Science Prize" (the "Challenge") to encourage and support the prototyping and development of services, tools and/or platforms that enable open content – including publications, datasets, code and other research outputs – to be discovered, accessed and re-used in ways that will advance research, spark innovation, and generate new societal benefits. The Challenge is necessary to accelerate the field of "open" biomedical research beyond what current funding mechanisms can achieve. For the NIH, this Challenge is being launched under

the America COMPETES Reauthorization Act of 2010.

1

DATES:

February 29, 2016: Phase I submissions due

April 30, 2016: Announce Phase I winners; Phase II begins

December 1, 2016: Phase II submissions due

February 28, 2017: Phase II winner announced

The NIH will announce any changes to the timeline by amending this Federal

Register notice.

ADDRESSES: To register for this Challenge, Challenge participants may access the

registration on the Challenge website (www.openscienceprize.org). Access to this

website may also be found by searching the www.challenge.gov site for the "Open

Science Prize."

FOR FURTHER INFORMATION CONTACT: Audie A. Atienza, Ph.D. (NIH),

Audie.Atienza@nih.gov; Vinay Pai, Ph.D. (NIH), paiv@mail.nih.gov; David Carr

(Wellcome Trust), d.carr@wellcome.ac.uk.

SUPPLEMENTARY INFORMATION:

Subject of Challenge

In order to stimulate innovation, the National Institutes of Health (NIH) Office of

the Associate Director for Data Science (ADDS), in conjunction with Challenge Partners,

the Wellcome Trust (WT) and the Howard Hughes Medical Institute (HHMI), is

2

launching the "Open Science Prize" (the "Challenge"); a prize competition to inspire the prototyping and development of services, tools, or platforms that enable open content — including publications, datasets, code and other research outputs — to be discovered, accessed and re-used in ways that will advance research, spark innovation and generate new societal benefits. The NIH is using the America Creating Opportunities to Meaningfully Promote Excellence in Technology, Education, and Science (COMPETES) Reauthorization Act of 2010 to support this Challenge.

The goal of this Challenge is to stimulate the development of novel and ground-breaking tools and platforms to enable the reuse and repurposing of open digital research objects (e.g. data, publications, other research outputs) relevant to biomedical or health applications. The volume of digital objects for research available to researchers and the wider public is greater now than ever before, and so, consequently, are the opportunities to mine and extract value from existing open content and to generate new discoveries and other societal benefits. A key obstacle in realizing these benefits is the discoverability of open content, and the ability to access and utilize it.

This Challenge provides a new and innovative avenue for developing the best ideas in this arena. Through the Challenge, the NIH, WT, and HHMI hope to encourage novel ideas and innovations that seek to unlock the vast potential benefits of making biomedical/health content and data open and re-useable, to demonstrate the huge potential value of open science approaches, and to generate excitement, momentum, and further investment. This Challenge also encourages international collaborations among technology innovators, health researchers, and biomedical informatics entities to address "Open Science" development. In building partnerships between innovators in the U.S.

and abroad, unique resources can be combined and leveraged to facilitate global health research objectives relevant to the mission of the NIH, increase rapid adoption of Open Science research tools across the globe, and enhance the generalizability of data sharing among researchers and practitioners internationally.

The NIH, WT, and HHMI are seeking to utilize the developer challenge model in the area of "Open Science" that is as open, flexible, and interactive as possible, so as to encourage the development of new collaborations as well as new ideas. Solvers are invited to use innovative approaches to develop applications and platforms that integrate, repurpose and/or repackage open digital resources relevant to health and biomedical research. The Challenge is open both to those who have new ideas and require some funding to take it to the prototype stage, and those with initial early-stage prototypes who wish to develop them further for cross-national or international adoption.

There will be two (2) phases to this Challenge. For Phase I, Solvers will submit written proposals for prototype designs and development plans to enable the reuse and repurposing of open digital research objects relevant to biomedical or health applications. For Phase II, Solvers (i.e., Phase I finalists) will submit their prototypes.

Statutory Authority

Pursuant to Section 402 of the Public Health Service Act, 42 U.S.C. § 282(b)(12), the NIH is authorized to reserve funds to provide for research on matters that have not received significant funding relative to other matters, to respond to new issues and scientific emergencies, and to act on research opportunities of high priority. The Open Science Prize is designed to incentivize innovation at the intersection of Open Science

(i.e., making scientific data and research outputs available and accessible to all levels of society) and Data Science (i.e., developing and utilizing research methods and designs that optimize the exploration and analysis of complex and/or large data sets; biomedical data in this case). Open Science and Data Science are two emerging fields within biomedical research and represent research opportunities of high priority within the NIH.

Official Rules

- 1. To Participate. This Challenge is open to any "Solver" where "Solver" is defined as (a) a group of individuals where at least one individual is a citizen or permanent resident of the United States, and at least one individual is citizen or permanent resident from a country other than the United States; or (b) a group of two or more public or private entities where at least one entity is incorporated in and maintains a primary place of business in the United States, and at least one entity is incorporated in and maintains a primary place of business in a country other than the United States. Phase II of this Challenge is open to Phase I winners only. Individuals participating in the Challenge who are younger than 18 years of age, whether as part of a team of individuals or a team of entities, must have their parent or legal guardian complete the Parental Consent Form found at www.openscienceprize.org.
- Eligibility Rules for Winning the Challenge. To be eligible to win a prize for this
 Challenge, the Solver and its members, as applicable, shall have complied with all the
 Official Rules.
- 3. In addition to satisfying the above eligibility requirements
 - a. The Solver shall have registered to participate in the Challenge under the rules

- promulgated by the sponsoring organizations (NIH, WT, HHMI) (as published in this notice);
- b. The Solver shall have complied with all the requirements under this section;
- c. The Solver, including each entity member, may not be a U.S. federal entity;
- d. The Solver, including each individual member, may not be a U.S. federal employee acting within the scope of his or her employment and further, in the case of the U.S. Department of Health and Human Services employees may not work on their Entries during assigned duty hours. **Note**: Federal ethical conduct rules may restrict or prohibit U.S. federal employees from engaging in certain outside activities, so any federal employee not excluded under the prior paragraph seeking to participate in this Challenge outside the scope of employment should consult his/her agency's ethics official prior to developing an Entry; and
- e. The Solver, including each individual member, may not be an employee of the NIH, a judge of the Challenge, or any other party involved with the design, production, execution, or distribution of the Challenge or the immediate family member of such a party (i.e., spouse, parent, step-parent, or step-child). Without limiting the generality of the foregoing, Expert Science Advisors who will provide comments on the entries and the NIH Judges, as well as their students, are not eligible to participate in the Challenge.
- f. **Note on Awards**: Monetary prizes provided by the WT and HHMI for the Challenge will be awarded separately from the NIH monetary prizes.
 - i. NIH monetary prizes: In the case of individuals participating on a team of

individuals, only individuals who are citizens or permanent residents of the United States are eligible for the NIH monetary prizes. Individuals who are not citizens or permanent residents of the United States can participate as a member of a team that otherwise satisfies the eligibility criteria but will not be eligible to win an NIH monetary prize (in whole or in part); however, their participation as part of a winning team, if applicable, may be recognized by the NIH when results are announced. In the case of private entities participating on a team of entities, only entities incorporated in and maintaining a primary place of business in the United States are eligible for the NIH monetary prizes. Private entities that are not incorporated in and do not maintain a primary place of business in the United States will not be eligible to win an NIH monetary prize (in whole or in part); however, should such an entity collaborate with a winning, and otherwise eligible, team such an entity may be recognized by the NIH when results are announced.

- ii. WT/HHMI monetary prizes. U.S. citizenship/residency (for individuals) or U.S. incorporation/place of business (for entities) is not a requirement to be eligible for the monetary prizes awarded by WT/HHMI.
- 4. Federal grantees may not use federal funds (e.g., NIH grants) to develop Challenge Entries unless consistent with the purpose of their grant award and specifically requested to do so due to the Challenge design, and as announced in the Federal Register.
- 5. Federal contractors may not use federal funds from a contract (e.g., NIH contract) to

- develop Challenge Entries or to fund efforts in support of a Challenge Entry.
- 6. Any Solver that is or has a member currently on the Excluded Parties List

 (https://www.sam.gov/sam/transcript/Public Identifying Excluded Entities.pdf & http://www.epa.gov/isdc/exclude.htm) will not be selected as a prize winner.
- 7. Entries must not infringe upon any copyright or any other rights of any third party.
- 8. A Solver shall not be deemed ineligible to win because the Solver used U.S. federal facilities or consulted with U.S. federal employees during the Challenge, provided that such facilities and/or employees, as applicable, are made available on an equitable basis to all Solvers participating in the Challenge.
- 9. Each Solver agrees to follow applicable local, state, and federal laws, regulations, and policies.
- 10. Each Solver must comply with all terms and conditions of these rules, and participation in this Challenge constitutes each such Solver's full and unconditional agreement to abide by these rules, which may also be found on the Challenge website (www.openscienceprize.org). Winning is contingent upon fulfilling all requirements herein.
- 11. The NIH reserves the right, in its sole discretion, to (a) cancel, suspend, or modify the Challenge, and/or (b) not award prizes if no Entries are deemed worthy.

All questions regarding the Challenge should be directed to Dr. Atienza, Dr. Pai, or Mr. Carr identified above, and answers will be posted and updated as necessary at (www.openscienceprize.org) under Frequently Asked Questions.

Registration Process for Participants

To register for this Challenge, Solvers may access the registration on the Challenge website (www.openscienceprize.org). Access to this website may also be found by searching the www.challenge.gov site for the "Open Science Prize". As described above in the eligibility section of the Official Rules, Solvers must establish an international collaborative team; specifically, either (a) a team of two or more individuals where at least one individual is a citizen or permanent resident of the United States, and at least one individual is citizen or permanent resident from a country other than the United States; or (b) a group of two or more public or private entities where at least one entity is incorporated in and maintains a primary place of business in the United States, and at least one entity is incorporated in and maintains a primary place of business in a country other than the United States. Additional details about participating as a team are provided below:

- 1. Each team must have two team leaders; one from the U.S. and one from outside of the U.S.
- 2. All members of the team need to be listed during registration.
- 3. There is no maximum team size.

<u>Challenge Entries</u>

As used in this notice, "Entry" is the information submitted in the manner and format specified on the "Open Science Prize" website (www.openscienceprize.org)

including without limitation computer programs, source code and object code. All Entries must be received by the applicable deadline. Entries submitted after a posted Challenge deadline will not be considered.

Entries may be submitted on behalf of a team by any of its members. It is up to each team to organize its Entry(ies) and to follow the Challenge submission requirements. On submission of an Entry of the Challenge, the Solver must include the team name under which the Entry is submitted.

All final Entries must be submitted through the Challenge website, following website instructions and should provide necessary and sufficient detail and annotation for reproduction of the submitted results.

Information accompanying each Phase I Entry should include:

- 1. Title of project.
- 2. Name of team.
- 3. Names, field of expertise and residency of the Solver's team members.
- 4. A written proposal describing the solution, no longer than 15,000 characters (not including spaces). This should include: an executive summary of 300 words maximum; identification of open content to be used; and a description of if, how, and under what license terms the team intends to make any of the computer code that is part of the Entry available to the public. Note:

 Executive summaries for all applications will be shared via the prize website without exception and licensed under the Creative Commons Attribution 4.0

 License (CC BY 4.0), so applicants should not include proprietary information

in their summary or any other information they are not prepared to be openly available.

- 5. Link to a web presence of the proposed solution.
- 6. Information about how the Solver learned about the Challenge.

Information accompanying each Phase II Entry should include:

- 1. Title of project.
- 2. Name of team.
- 3. Names, field of expertise and residency of Solver's team members.
- 4. Description/specification of the prototype developed and potential future impact of the prototype, no longer than 15,000 characters (not including spaces).
- 5. Link to a web presence of the prototype.
- 6. Website URL to access the prototype and relevant instructions (1 page).

Only complete Entries, which follow application instructions, will be reviewed and eligible to win. The NIH and Challenge Partners reserve the right to disqualify any Challenge participants in instances where cheating or other misconduct is identified.

Details regarding the dispute resolution process are provided on the Challenge website (www.openscienceprize.org).

Warranties

By submitting an Entry to the Challenge, each Solver represents and warrants that all information provided in the Entry and as a result of the Challenge registration process

is true and complete, that Solver has the right and authority to submit such Entry on the Solver's own behalf or on behalf of the persons and entities specified within the Entry, and that the Entry:

- 1. Is the Solver's own original work, or is used by permission with full and proper credit given within the Entry;
- 2. Does not contain confidential information or trade secrets (the Solver's or anyone else's);
- Does not violate or infringe upon the patent rights, industrial design rights,
 copyrights, trademarks, rights of privacy, publicity or other intellectual property
 or other rights of any person or entity;
- Does not contain malicious code, such as viruses, timebombs, cancelbots, worms, trojan horses or other potentially harmful programs or other material or information;
- 5. Does not and will not violate any applicable law, statute, or regulation; and
- 6. Does not trigger any reporting or royalty obligation to any third party.

Amount of the Prize

During Phase I, up to six (6) winners may be identified. The NIH may award up to three (3) winning teams monetary prizes of \$80,000 per team. The WT/HHMI may award up to three (3) winning teams monetary prizes of \$80,000 per team.

During Phase II, one (1) Entry will be awarded a grand prize of up to \$230,000. The NIH will award \$115,000 to the U.S. member(s) of the winning team, and the

WT/HHMI will award \$115,000 to the winning team. For the NIH awards, prizes will be awarded by the NIH Contractor, Capital Consulting Corporation.

The top 6 Entries (grand prize winner and the 5 runner-ups) may be highlighted on the Challenge and the NIH ADDS websites pending selection by the NIH.

The NIH reserves the right to cancel, suspend, and/or modify this Challenge at any time through amendment to this <u>Federal Register</u> notice. In the event the Challenge is modified, Solvers registered in the Challenge will be notified by email and provided with a copy of the amended Challenge rules and a listing of the changes that were made. Any Solver who continues to participate in the Challenge following receipt of such a notice of amendment(s), will be deemed to have accepted any such amendment(s). If a Solver does not wish to continue to participate in the Challenge pursuant to the Official Rules, as amended, such Solver may terminate participation in the Challenge by not submitting additional Entries. The NIH reserves the right to not award prizes if no Entries are deemed worthy.

Basis upon Which Winner Will Be Selected

Entries will be scored by the Challenge Judges using the criteria listed below.

• Advancement of Open Science – To what extent does the proposal/prototype advance the goals of open science in biomedical/health research, and fulfill the goals of openness in terms of the product and way of working? To what extent would it move the field forward?

- Impact What level of impact and benefit could the proposal if successful deliver to the research enterprise and health research? Does the proposal/prototype address implementation in multiple settings in a cross-national manner?
- Innovation What level of creativity and technological innovation does the entrant demonstrate?
- Originality Is the technology or service genuinely novel and targeting an unmet need? Has the applicant evaluated other existing or alternative approaches, or delineated their approach in comparison to existing approaches (if applicable)?
- Technological viability Is the approach proposed viable? Can the proposed technology deliver?
- Resource feasibility Does the team have the required skills and resources?

Judges will rate each entry on five-point scale from Not-fundable (1) to Outstanding (5). The NIH and WT will hold separate judging panels, and then will discuss priorities for selection of the respective winners (in Phase I), and the final winner (in Phase II).

For Phase II, public voting will select the top 3 prototypes of the 6 Phase I finalist, followed by a review of the prototypes for feasibility and technical merit by external advisors with expertise in Open Science. Prototypes will then be scored by Judges using the initial Phase I criteria.

Intellectual Property

By submitting an Entry, each Solver warrants that he or she is the sole author and

owner of any copyrightable works that the Entry comprises (or has obtained sufficient rights in any copyrightable works owned by third parties to satisfy its obligations set forth herein), that the works are wholly original with the Solver (or is an improved version of an existing work that the Solver has sufficient rights to use and improve), and that the Entry does not infringe any copyright or any other rights of any third party of which Solver is aware.

To receive an award, Solvers will not be required to transfer their intellectual property rights to the NIH or the Challenge Partners. Each Solver retains title to their Entry, including object and source code, and expressly reserves all intellectual property rights (e.g., copyrights and rights to inventions and patents that cover them) in their Entry, unless the Solver chooses an open license for the Entry. By participating in the Challenge each Solver grants to the U.S. government a nonexclusive, non-transferrable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any invention throughout the world owned or controlled by the Solver that covers the Entry, and grants to the U.S. government and others acting on behalf of the U.S. government, a royalty-free, irrevocable, non-exclusive worldwide license to use, reproduce, and display publicly all parts of the Entry for the purposes of the Challenge. This license includes without limitation posting or linking to the Entry on the official Challenge website and, except for object code or source code, making the Entry available for research use by the public. Notwithstanding the above and consistent with the principal objective of the challenge to make results widely available to the public, the NIH encourages the Solver to distribute any computer code (object code and preferably also source code) that is part of the Entry to the public under a liberal open source license

that permits the public to benefit from and improve upon the Entry (see the licenses available at http://opensource.org/licenses/). The Solver should include in its submission a description of how and under what license terms it intends to make any computer code that is part of the Entry available to the public.

Solvers are free to discuss their Entry and the ideas or technologies that it contains with other parties, encouraged to share ideas/technologies publicly, and are free to contract with any third parties, as long as they do not sign any agreement or undertake any obligation that conflicts with the Challenge rules set forth herein. For the purpose of clarity, Solvers acknowledge that the intent of the Challenge is to encourage people to collaborate and share ideas and innovations.

Liability and Indemnification

By participating in this Challenge, each Solver agrees to assume any and all risks and waive claims against the U.S. federal government and its related entities (as defined in the COMPETES Act), including Capital Consulting Corporation, the Challenge Expert Science Advisors and Judges, except in the case of willful misconduct, for any injury, death, damage, or loss of property, revenue, or profits, whether direct, indirect, or consequential, arising from participation in this Challenge, whether the injury, death, damage, or loss arises through negligence or otherwise. By participating in this Challenge, each Solver agrees to indemnify the federal government and the Capital Consulting Corporation against third party claims for damages arising from or related to Challenge activities.

<u>Insurance</u>

Based on the subject matter of the Challenge, the type of work that it will possibly

require, as well as an analysis of the likelihood of any claims for death, bodily injury, or

property damage, or loss potentially resulting from competition participation, Solvers are

not required to obtain liability insurance or demonstrate financial responsibility in order

to participate in this Challenge.

Date: September 28, 2015

Lawrence A. Tabak, D.D.S., Ph.D.

Deputy Director

National Institutes of Health

[FR Doc. 2015-26392 Filed: 10/19/2015

08:45 am; Publication Date: 10/20/2015]

17